



NEW DRUG

Safety

Efficacy

Dosage

Drug Interactions

Indications

Precautions

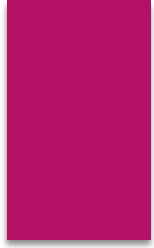


RESEARCH DESIGNS

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In many ways the design of a study is more important than the analysis. A badly designed study can never be retrieved, whereas a poorly analysed one can usually be reanalysed. Consideration of design is also important because the design of a study will govern how the data are to be analysed.

- Statistics at Square One
Ninth Edition
T D V Swinscon, BMJ

RESEARCH DESIGNS

OBSERVATIONAL

ANALYSIS OF
PUBLISHED RESEARCH

INTERVENTIONAL

DESCRIPTIVE

ANALYTICAL

NON
RANDOMIZED

RANDOMIZED

- Case reports
- Case series
- New Interventions

Diagnostic Test
Evaluation

- Ecological Studies
- **Cross Sectional**
- Case control
- Cohort
- Case – cohort
- Audits
- Validating Prediction tools
- **Surveys**

- Un randomized
- Quasi randomized
- Before - after

- Factorial
- Cluster randomization
- Stepped wedge design

Case reports , Case series

- ▶ June 5, 1981, *MMWR* - five cases of *Pneumocystis carinii* pneumonia (PCP) among previously healthy young men in Los Angeles
- ▶ "homosexuals"; two died
- ▶ "cellular-immune dysfunction related to a common exposure" ,
- ▶ "disease acquired through sexual contact."
- ▶ In March 1983, CDC issued recommendations for prevention of sexual, drug-related, and occupational transmission based on these early epidemiologic studies and before the cause of the new, unexplained illness was known.

Analytical studies

- ▶ *Ecological Studies*
- ▶ “aggregate risk studies” - measure exposure status and outcome status as average values across groups of individuals
- ▶ “Ecological fallacy,”
- ▶ **Cross-sectional studies**
- ▶ assess the exposure status and outcome status of individuals at the same time (or within a short and stable interval).
- ▶ exposures that do not change over time (genetically-determined characteristics or chronic stable health conditions.)
- ▶ No causality (Bradford Hill criteria)

Case – Control , Cohort

- ▶ **Case – control**
- ▶ Outcome to exposure
- ▶ inexpensive, amenable to quick completion, and suited to the study of rare outcomes - postoperative stroke
- ▶ Recall , Selection bias
- ▶ **Cohort**
- ▶ Exposure to outcome
- ▶ Prospective , Retrospective , Case – Cohort (matching)
- ▶ Direction , casualty , expensive , resource consuming , rare diseases - na

Audit, Surveys

- ▶ **Studies Assessing Practice Against a Gold Standard (“Audit”)**
- ▶ Assembling a cohort of patients and determining whether practice complies with an external standard.
- ▶ **Surveys**
- ▶ Surveys collect information from individuals (patients, families, staff, students) or organizations (hospitals, universities, employers) about facts and attitudes
- ▶ cross-sectional studies assessing exposures and outcomes at the same time.
- ▶ Factual , Attitudinal surveys
- ▶ Surveys can be descriptive (describing responses from the whole group) or analytic (comparing responses in sub-groups).

Unrandomized Studies

- ▶ Investigator allocates the intervention or control to study patients in a nonrandom manner - selection bias
- ▶ Overestimation or underestimation of the true treatment effect may occur.
- ▶ **Quasi-Randomized Studies**
- ▶ Quasi-randomized (or quasi-experimental) studies attempt to select patients for the intervention or control in a less obvious but still nonrandom manner, for example, by surgical specialty, day of the week, date of birth, or by using a cut-off score for a certain characteristic.

Randomized trials

- ▶ Parallel, Cross Over
- ▶ Confounders
- ▶ **Factorial Designs**
- ▶ Factorial designs allow testing of more than one intervention in a single clinical trial.
- ▶ Rather than performing a separate randomized trial for each intervention and each combination, patients in factorial studies are separately randomized to two or more different interventions (that is, they receive none, some, or all of the experimental interventions).
- ▶ efficient and allows testing of interactions between the interventions.

Cluster Randomized Designs

- ▶ patient level
- ▶ randomization at the patient level is not possible or is methodologically unsound.
- ▶ Community based interventions , execution by the treating team and blinding is often not possible
- ▶ **Stepped Wedge Designs**
- ▶ A stepped wedge design circumvents some of these ethical and methodological issues by ensuring that each cluster first provides data for the control condition and then crosses over to the new intervention
- ▶ The duration of these periods differs for every cluster, but at the end of the study period there will be an equal amount of data from control and intervention periods.
- ▶ Stepped wedge designs were originally used in vaccination studies.
- ▶ They are considered alternatives for randomized trials of complex interventions, provided that there is a high likelihood of a positive effect of the intervention and a very low risk of harm.

Analyses of Published Research

- ▶ **Systematic Reviews**

- ▶ Systematic reviews pose an explicit research question and publish a transparent search strategy that every reader can replicate and update.

- ▶ **Metaanalyses**

- ▶ When multiple studies have addressed similar research questions, interventions, and outcomes, the results can be mathematically aggregated in a metaanalysis

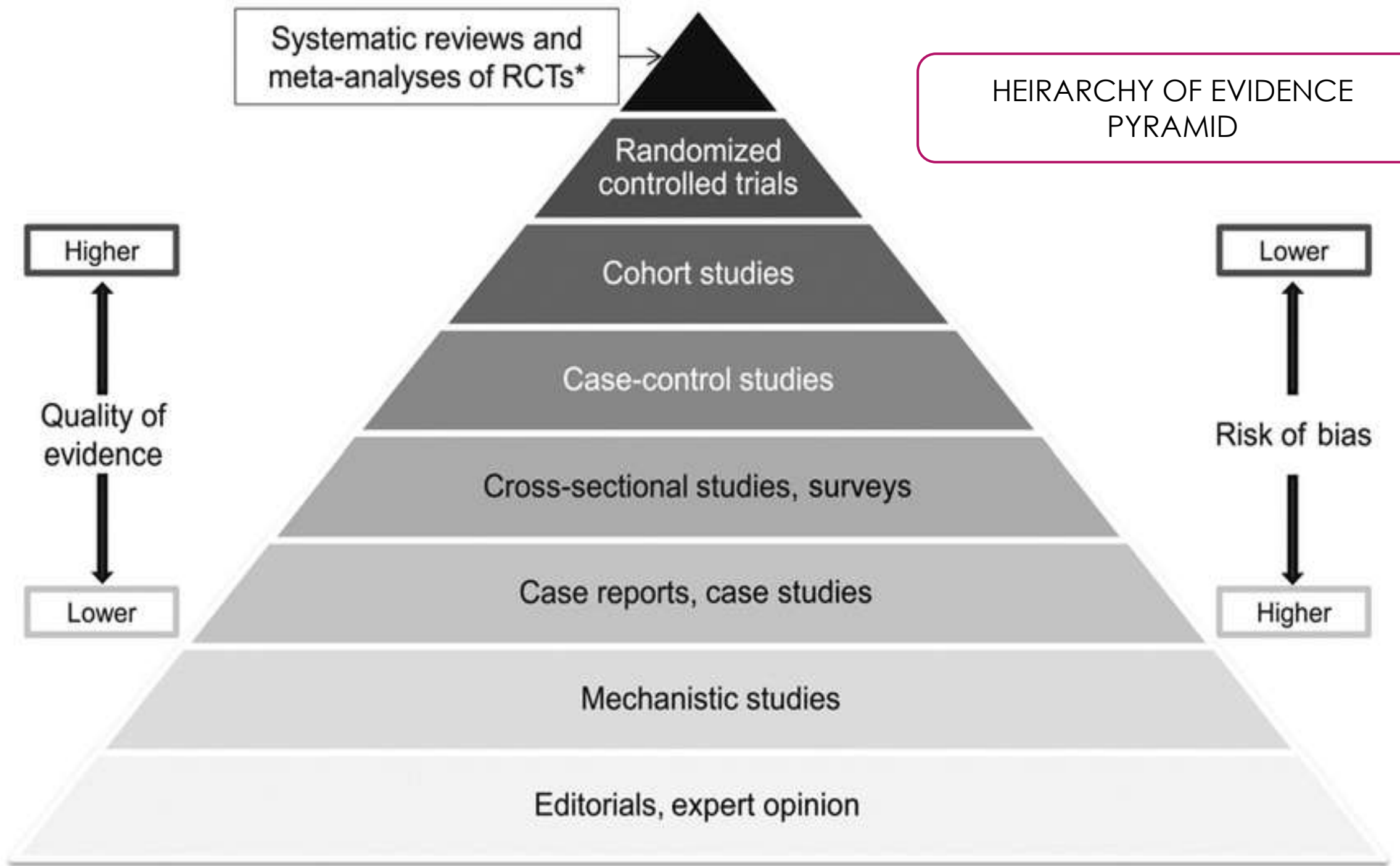
- ▶ A high-quality metaanalysis of large well-conducted randomized trials is considered the highest level of evidence to guide practice, although results of metaanalyses do not always agree with subsequent very large trials.

Things to consider

- ▶ Aim of the study
- ▶ HYPOTHESIS
- ▶ Logistics
- ▶ Ethical concerns

Systematic reviews and meta-analyses of RCTs*

HEIRARCHY OF EVIDENCE
PYRAMID



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THANK YOU